Rep. Henry A. Waxman
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Biosimilar Drug Development World Americas
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I am pleased to join you today, even if only by video, as we approach the 30th anniversary of the Waxman Hatch Act. I want to thank Health Network Communications for holding this important conference. I always look forward to opportunities to applaud the generic drug industry for its tremendous work in bringing safe, effective, and low-cost drugs to American consumers, and to the world over.

Who would have thought, in 1984, that thirty years later eighty per cent of all U.S. prescriptions would be filled by generics? I don't think anyone could have imagined that generic medicines would now be saving the U.S. healthcare system and consumers almost $200 billion dollars per year. And as we move into this new era of medicine marked by the ever-increasing presence of cutting-edge, and incredibly expensive, biologics, your efforts will continue to play a critical role in keeping our healthcare bill down.

Generic Drug and Biosimilar User Fees

This meeting is coming at the end of a rather disheartening year for Congress, to put it mildly. The federal government shutdown resulted in the loss to our economy of about $24 billion dollars and, according to a recent study by the Council of Economic Advisers, about 120,000 jobs. The shutdown came on top of budget sequestration, which has had a devastating impact throughout the government. For FDA, sequestration has resulted in a cut of over $200 million from FDA's funding this year, including a loss of $56 million in user fees.

Industry still has to pay the full user fees, but the money sits unavailable in an FDA account. The money cannot collect interest, and even if sequestration ends, FDA will not have access to the money unless Congress newly appropriates it for FDA use. This makes no sense: industry pays, but FDA can't use the money. There is bipartisan legislation to remedy the user-fee problem, the FDA Safety Over Sequestration Act, or "FDA SOS Act", of which I am a co-sponsor. To date, Congress has not taken it up, but I'm hopeful we will see movement soon.

Sequestration was bad news for all of the areas funded by user fees, but particularly for the newly established generic drug user fee program. As you know, in last year's FDA Safety and Innovation Act or FDASIA, Congress finally acted to create a generic user fee program to address what had become a large backlog of applications and an unreasonably long wait for the review of ANDAs (Abbreviated New Drug Applications).

The good news is that, even in the face of the sequester and the government shutdown, FDA has been making steady progress on the backlog. So far, FDA has reviewed more than 40% of the 2,500 backlogged applications. It has also hired over 230 new people, and is on track to meet its goal of hiring a total of over 900 new workers for its generic drugs program by the end of 2015.

The fees are also enabling FDA to conduct more safety inspections of manufacturing facilities abroad. Under the agreement, for the first time FDA will hold foreign and domestic facilities to the same risk based inspection standards.

I will continue to be on the lookout to ensure FDA's user fee programs are functioning as we intended and helping to bring low-cost generic and biosimilar medicines to the market at the earliest possible time.

Biosimilars

Another area that I have been and will continue to be closely watching is implementation of the Affordable Care Act's biosimiliar pathway. Obviously, we didn't get everything we wanted in that legislation. I, of course, would have preferred a pathway that ensured more competition would be brought to bear in this market at a much earlier date. But it is important to ensure the provisions we ended up with function as effectively as possible. As we all know, the brand industry continues its quest to tilt biosimilar policy in its favor. We need to work to prevent the imposition of unnecessary barriers or disincentives to the use of biosimilars.

One critical question FDA is facing as it puts the ACA provisions in place is whether biosimilars should be required to have non-proprietary names, or "International Nonproprietary Names" ("I-N-N"), distinguishable from that of their reference product. Requiring a different I-N-N could make it more difficult for interchangeable biologics to be substituted at the pharmacy level. Obviously, a huge part of the success of the traditional generic drug marketplace is the ability for automatic substitution at the pharmacy level to occur. So, if there is a different I-N-N, interchangeable biosimilars could be impeded from achieving their full potential to bring down the costs of new biotech medicines.

On the other hand, I think FDA has got to be confident that having the same I-N-N would not lead to increased patient confusion or medication errors. FDA must also be assured that the same I-N-N will not interfere with the ability of FDA and manufacturers to track adverse events.

This is a complicated and difficult issue. But I believe FDA will carefully consider it and resolve it in a way that both protects patients and ensures their access to these important medicines.

The brand industry has also been relentlessly pursuing efforts to weaken the ACA's biosimilar pathway at the state level. BIO has succeeded at getting various states to enact laws that will impede patient access to biosimilars by, for example, requiring physician notification by a pharmacy before an interchangeable biosimilar can be dispensed. These policies are being touted by supporters as benign steps to simply protect patients and keep physicians in the loop. We all know they are actually efforts to scare patients and physicians into thinking there is something wrong or different about these interchangeable drugs.

I was pleased to see that Governor Jerry Brown recently vetoed one example of such legislation in California. I know GPHA, payers, and others have been vigilantly defending against these attempts. I urge you all to keep up the fight at the state level.

There is little dispute that biologics are part of the future of medicine. But these life-saving therapies will be worth little if no one can afford them. So we need to make sure that policies are in place that will permit biosimilars to fulfill their potential to bring competition to bear in this market. I will continue to do my best to ensure that the biosimilars pathway is effective and results in meaningful cost-savings for Americans.

Drug Shortages

Another issue that affects patients on a daily basis is the problem of drug shortages. We have witnessed shortages affecting a broad spectrum of critically important drugs, including anti-cancer drugs and antibacterial drugs. Many drugs in shortage are generic sterile injectables, so clearly your industry plays a vital role in helping to alleviate shortages for certain types of drugs.

FDA tells us that manufacturing problems are the most common causes of temporary supply interruptions with respect to sterile injectable drugs. These manufacturing problems have presented significant health hazards, like contamination with glass shards.

I recognize that manufacturing sterile injectable drugs is a challenge for many generic companies. [It is expensive to maintain sterile lines and the protecting against contamination takes a great deal of vigilance. As with all other generic drugs, the profit margin at the end of the day is not nearly as high as it might be for an equivalent brand sterile injectable.] A recent announcement by Ben Venue Laboratories that by the end of the year it will stop manufacturing generic injectable drugs, most of which are cancer drugs, is an illustration of this point and a reminder that the drug shortage problem is far from over.

But American patients need you to keep producing these life-saving drugs. So we all need your help in finding ways to address this problem.

Last year's FDASIA legislation took one major step to address the shortages by requiring companies to notify FDA when there is an impending interruption in their supply of critical drugs. With such advance notice, FDA can work with companies to avoid or ameliorate the shortage.

FDA also recently released its Drug Shortages Strategic Plan and a proposed rule addressing the discontinuation or interruption of manufacturing of certain drugs, as required by FDASIA. The Strategic Plan includes a discussion of the need to develop and use incentives that would encourage redundancy in manufacturing capacity and capability, as well as in other investments in manufacturing facilities.

Obviously, your industry is best positioned to understand what such incentives might be and how they might work. I hope you will continue to work with FDA and other stakeholders to identify workable incentives that would help alleviate this situation.

I know GPhA has also dedicated a great deal of effort to its Accelerated Recovery Initiative to complement the notification provisions in FDASIA. I applaud you for your efforts and I stand ready to continue to work with you to take steps to address this serious public health problem.

Drug Quality and Security Act

I know many of you have been watching developments with respect to the Drug Quality and Security Act, which is one of the few bipartisan achievements of this session. The House passed the bill by voice vote in early October, and it passed the Senate just two days ago. The legislation addresses two distinct areas, pharmacy compounding and the security of the drug supply chain.

Pharmacy Compounding

The need to improve the oversight of compounded drugs was made starkly clear by the fungal meningitis outbreak of a year ago. It was the largest outbreak of healthcare associated infections ever reported in U.S. history. Over thirteen thousand people received injections with potentially contaminated drug made by the New England Compounding Center (NECC) of Massachusetts. Of these, so far sixty four people have died and over 750 have gotten spinal meningitis or other infections.

Members on both sides of the aisle, and in both houses of Congress, came together to try to figure out how to prevent another such tragedy.

One thing was clear: FDA's authorities over compounding pharmacies were not up to the task. Divergent court decisions on the underlying statute had forced the agency to cobble together a piecemeal approach to regulating compounding pharmacies that was different in some parts of the country than in others. That untenable legal situation created loopholes that companies like the NECC were able to exploit.

FDA was also facing a compounding industry that had dramatically changed since 1997, when Congress last legislated on compounding. Hospitals have grown dependent on so-called "outsourcers," which are very large compounders that mix batches of customized drugs for a particular hospital.

The legislation we passed will take a major step toward addressing these issues. It will correct the constitutional defect in underlying law that has wreaked havoc on FDA's ability to effectively enforce the law. It also will give hospitals and doctors the ability to get compounded medicines from facilities that are subject to stringent FDA quality standards and oversight. All other compounding pharmacies will continue to be subject to current law.

I know many of you were concerned, as was I, that legislation establishing a category of compounder that would receive FDA oversight might undermine the FDA drug approval system. It could essentially create a new tier of manufacturers who did not have to meet the rigorous

approval and manufacturing standards required of all other drug manufacturers, giving those in this new tier an unfair marketing advantage over both generic and brand manufacturers. I think the legislation successfully avoided that potential problem by including safeguards, such as a prohibition on making copies of FDA-approved drugs except in the case of an ongoing drug shortage.

Drug Supply Chain

The Drug Quality and Security Act also contains a drug supply chain component that builds on bipartisan, bicameral work from last year. The new legislation will establish an electronic, interoperable system at the federal level within ten years. The system will track each package of drugs, at the unit level, throughout the entire supply chain. This will help prevent Americans from being harmed by counterfeit and substandard medicines. It will make it much harder for criminals to introduce such drugs into the supply chain, and it will facilitate the rapid trace-back and removal of adulterated or counterfeit drugs that get into the supply chain.

The Drug Quality and Security Act is a bipartisan bill that I think we can all be proud of. I know the generic drug industry worked hard with our committee, and with the Senate HELP committee, to ensure that both the compounding and drug supply chain components of the legislation would protect public health and would be workable. I commend you for that.

Conclusion

As all of you well know, the availability of high quality generic drugs is good for people all over the world. It is one of the most effective ways to hold down the costs of health care that we know. That is why I will continue to work to promote competition and innovation in our prescription drug industry and to increase the use of generic medicines worldwide.

I applaud all of you for the work you do every day to achieve this goal. And I thank you for this opportunity to speak with you.